

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	)	
	)	
Inhee Lee, et al.	)	
	)	Examiner: Taofiq A. Solola
Application No.: 10/500,023	)	
	)	Art Unit: 1625
Filed: March 7, 2005	)	
	)	
For: NEW PROCESS FOR THE	)	Conf. No.: 2721
PREPARATION OF OPTICALLY	)	
ACTIVE 2-[6-(SUBSTITUTED	)	Date of NOA: 12/12/06
ALKYL)-1,3-DIOXAN-4-YL]	)	
ACETIC ACID DERIVATIVES	)	
_____	)	

Office of Initial Patent Examination's  
Filing Receipt Corrections  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR CORRECTION OF FILING RECEIPT

Dear Sir:

On March 28, 2005 we received the Official Filing Receipt dated March 21, 2005 in connection with the above-referenced patent application (copy enclosed). However, Applicant respectfully notes that the following information needs to be corrected due to a PTO error regarding the patent application's title. Please change:

FROM:

**PROCESS FOR THE PREPARATION OF OPTICALLY ACTIVE 2-[6-SUBSTITUTED ALKYL)-1,3-DIOXAN-4-YL] ACETIC ACID DERIVATIVES**

TO:

**PROCESS FOR THE PREPARATION OF OPTICALLY ACTIVE 2-[6-(SUBSTITUTED ALKYL)-1,3-DIOXAN-4-YL] ACETIC ACID DERIVATIVES**

Therefore, correction with respect to the title of the invention listed in the Official Filing receipt of the present application is respectfully requested. Please correct the title as shown above. Enclosed is a copy of the title page of the application, a copy of the signed Declaration/Power of Attorney, and a copy of the filing receipt marked with the appropriate corrections.

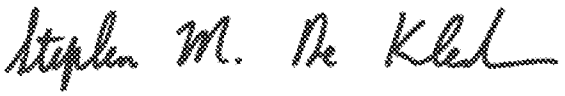
If there are any additional fees, please charge them to Deposit Account 02-2666.

If you have any questions, please contact the undersigned.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: March 9, 2007

  
/\_\_\_\_\_/

Stephen M. De Klerk

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# NEW PROCESS FOR THE PREPARATION OF OPTICALLY ACTIVE 2-[6-(SUBSTITUTED ALKYL)-1,3-DIOXAN-4-YL]ACETIC ACID DERIVATIVES

## TECHNICAL FIELD

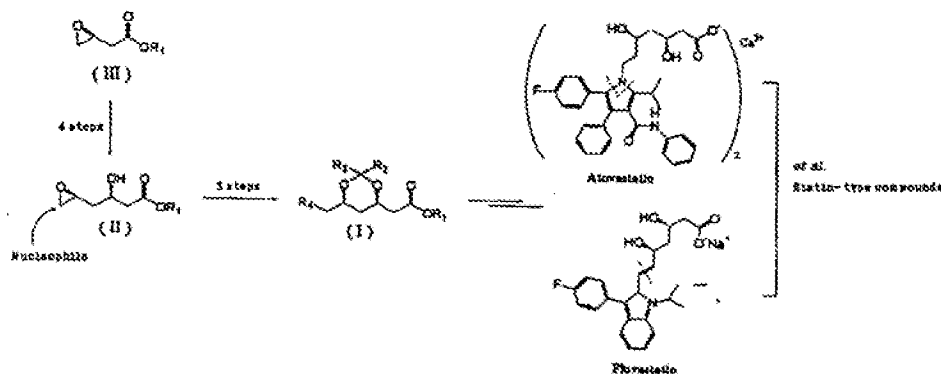
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The present invention relates to a process for preparing intermediates of pharmaceuticals, especially Statin-type pharmaceuticals such as Atrovastatin and Fluvastatin etc. or optically active 2-[6-(substituted alkyl)-1,3-dioxane-4-yl] acetic acid derivatives which are valuable as an intermediate of 3-hydroxy-3-methylglutaryl-coenzyme A(HMG-CoA reductase) repressor.

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More specifically, the present invention relates to a new process for preparing a compound of formula (I) by reacting optically active epoxy alcohol of formula (II) prepared from an optically active epoxy compound of formula (III) with various substituents.

### 15    【Scheme 1】



wherein R<sub>1</sub> denotes a hydrogen atom, alkyl, aryl or alkylaryl, preferably methyl, ethyl, isopropyl, or *tert*-butyl, R<sub>2</sub> and R<sub>3</sub> which can be identical or different, denote a lower alkyl or phenyl and are capable of forming a six-membered ring, R<sub>4</sub> stands for hydroxy, amino, alkylamino, arylamino, azido, cyano, halogeno, aryloxy, alkyloxy, arylalkyloxy, alkyl,

20

Attorney's Docket No.: 007137.P001

Patent

First Named Inventor: Inhee Lee

Check One:

☐ Declaration Submitted with  
Initial Filing OR  
☒ Declaration Submitted After  
Initial Filing (Surcharge under  
37 C.F.R. § 1.16(e) Required)

Complete If Known:

Application No.: 10/500,023  
Filing Date: June 21, 2004  
Art Unit: Not Yet Assigned  
Examiner Name: Not Yet Assigned

**DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION**

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

NEW PROCESS FOR THE PREPARATION OF OPTICALLY ACTIVE  
2-[6-(SUBSTITUTED ALKYL)-1,3-DIOXAN-4-YL] ACETIC ACID DERIVATIVES

(Title of the Invention)

the specification of which

☒ is attached hereto OR  
☐ was filed on (MM/DD/YYYY) 06/21/2004 as  
as United States Application Number 10/500,023  
or PCT International Application Number \_\_\_\_\_  
and was amended on (MM/DD/YYYY) \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above.

I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application. I do not know and do not believe that the claimed invention was in public use or on sale in the United States of America more than one year prior to this application, nor do I know or believe that the invention has been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			<u>Priority Claimed?</u>		<u>Certified Copy Attached?</u>	
<u>PCT/KR02/01540</u> (Number)	<u>PCT</u> (Country)	<u>08/13/2002</u> (Foreign Filing Date - MM/DD/YYYY)	<u>X</u> Yes	<u>      </u> No	<u>      </u> Yes	<u>X</u> No
<u>2001/81659</u> (Number)	<u>Korea</u> (Country)	<u>12/20/2001</u> (Foreign Filing Date - MM/DD/YYYY)	<u>X</u> Yes	<u>      </u> No	<u>      </u> Yes	<u>X</u> No
<u>                    </u> (Number)	<u>                    </u> (Country)	<u>                    </u> (Foreign Filing Date - MM/DD/YYYY)	<u>      </u> Yes	<u>      </u> No	<u>      </u> Yes	<u>      </u> No

#### **Appointment of Patent Practitioners:**

I hereby appoint the patent practitioners associated with the **Customer Number 08791** as my respective patent attorneys and patent agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected herewith.

If this patent application is assigned, then the undersigned hereby authorizes the patent attorneys and patent agents named herein to accept and follow instructions from the assignee(s) as to any action to be taken in the United States Patent and Trademark Office regarding this application without direct communication between the patent attorneys and patent agents and the undersigned. In the event of a change in the persons from whom instructions may be taken, at least one patent attorney or patent agent named herein will be so notified by the undersigned.

**Direct all correspondence to (check one):**

  X   **Customer Number 08791 OR**

       **Correspondence Address Below:**

Stephen M. De Klerk  
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Inhee LEE  
(Given Name (First and Middle (if any)), Family Name (or Surname), and Suffix (if any))

Inventor's Signature Inhee Date Sep. 17, 2004

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NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

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07137.001  
CNOONGWAE PHARM  
SMD

## UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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Alexandria, Virginia 22313-1450  
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APPL NO	FILING OR 371 (a) DATE	ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/500,023	03/07/2005	1626	1210	7137P001	1	11	2

CONFIRMATION NO. 2721

08791

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SEVENTH FLOOR  
LOS ANGELES, CA 90025-1030

## FILING RECEIPT



\*OC000000015478743\*

Date Mailed: 03/21/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

## Applicant(s)

Inhee Lee, Gyeonggi-do, KOREA, REPUBLIC OF;  
Seungjoo Lee, Gyeonggi-do, KOREA, REPUBLIC OF;

RECEIVED

MAR 28 2005

Power of Attorney: The patent practitioners associated with Customer Number 08791.

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP  
LOS ANGELES

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/KR02/01540 08/13/2002

ENTERED

MAR 29 2005

## Foreign Applications

REPUBLIC OF KOREA 2001/81659 12/20/2001

STATUS DB/LA

Projected Publication Date: 06/23/2005

Non-Publication Request: No

Early Publication Request: No

## Title

Process for the preparation of optically active 2-[6-(substituted alkyl)-1,3-dioxan-4-yl]acetic acid

derivatives

**Preliminary Class**

548

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

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